

Remarks

Introduction

Claims 36-40 are canceled, claims 21-35 and 41 are pending for examination and reconsideration, which are respectfully requested in view of the following remarks.

Priority

The Examiner maintains that priority application 08/985,526 (filed December 5, 1997 and issued as US Patent No. 6,080,728) ("the '526 parent application" or "the '728 patent") fails to provide support for claims 21-35 directed to the administration of RNA. Without acquiescing to the Examiner's position, applicant has amended the claims to delete the recitation of RNA. The Examiner also maintains that the '526 parent application fails to provide support for the administration of nucleic acid recited in claims 36-40. Without acquiescing to the Examiner's position, applicant has amended the claims to delete the claims reciting nucleic acid. The currently pending claims recite the administration of a nucleotide sequence. Literal support for "nucleotide" is found in the '526 parent application in, for example, column 9, line 4 of the '728 patent. Applicant submits that the term "nucleotide" has a well-known meaning in the art and refers to a chemical genus having specific structural properties and is understood by the skilled artisan to necessarily include both DNA sequences and RNA sequences. Therefore, applicant respectfully submits that the present claims which recite the administration of nucleotide sequences are fully supported by the '526 parent application and thus have the benefit of a priority date to at least as early as December 5, 1997, the filing date of the '526 parent application.

Double Patenting

The Examiner has rejected claims 36-40 under the doctrine of obviousness-type double patenting in view of claims 1-5 of the '728 patent. Without acquiescing in this rejection, applicant has rendered the rejection moot by the cancellation of the rejected claims. With regard to the currently pending claims, Applicant respectfully requests that this rejection be held in abeyance until the Examiner finds the claims in condition for allowance as is permitted under the M.P.E.P.

Claim Rejections Under 35 U.S.C. § 112, first paragraph

The Examiner alleges that claims 21, 23-26, 28-36 and 38-40 are not enabled by the specification. Specifically, the Examiner asserts that while the specification enables methods of intravenous or intratumoral administration, that the specification does not enable the skilled artisan as to "how to use" other methods of administration. For example, the Examiner maintains that:

One of ordinary skill in the art appreciates that subcutaneous administration ... is a local administration and will not result in delivery of nucleic acids to sites that than the administration site.
(page 4 of the Office Action)

Applicant respectfully traverses this rejection. To be enabling, the disclosure must contain sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. MPEP 2164.01. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *Id.* (quoting *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988)).

The Examiner has essentially stated that the claims are not enabled because subcutaneous administration would not be effective for treatment of tumors at sites distant from the administration site. Applicant respectfully traverses this rejection on two grounds. First, applicant submits that the administration would in fact be effective for subcutaneous administration. For example, subcutaneous administration adjacent to a tumor would be effective as would be subcutaneous administration into a site that is responsible for blood supply for a tumor. Applicant respectfully points to MPEP section 2164 which states that the Examiner has the burden to provide scientific evidence for why a claim is not enabled. Applicant respectfully submits that the Examiner has provided no such evidence.

Second, enablement must be viewed in terms of what the skilled artisan would understand. The skilled artisan would readily understand the advantages and disadvantages of

subcutaneous administrations and would now how to use the claimed invention subcutaneously for tumors for which such administration would be effective. The skilled artisan would similarly know when intratumoral or intravenous administration would be effective or when other methods of administration would be effective. The court has directly held that when it is within the ability of the skilled artisan, without undue experimentation, to determine whether a claimed embodiment will be effective or not, the claim is enabled. *See, e.g., In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988); *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976). Accordingly, Applicant respectfully requests that the enablement rejection be withdrawn with regard to the currently pending claims.

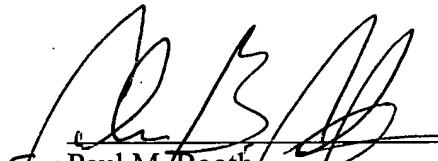
Claim Rejections Under 35 U.S.C. § 102 and Claim Rejections Under 35 U.S.C. § 103

The Examiner has rejected 36-39 as anticipated by Mixson (EP 0 819 758) published 1/21/98 and claims 21-24, 26-31, and 33-35 as obvious in view of Mixson (EP 0 819 758) combined with Lu *et al.* (*Cancer Gene Therapy* 1(4) 245-252). Applicant respectfully requests withdrawal of these rejections as applied to the currently pending claims. As discussed above, the current claims are supported by and have the benefit of priority to at least as early as the filing date of the '526 parent application, namely December 5, 1997. Accordingly, Mixson (EP 0 819 758) is not available as prior art to the claims and applicant respectfully maintains that the rejection should be withdrawn.

CONCLUSION

Notification of allowance of the claims is respectfully requested and should the Examiner have any questions regarding the instant paper, the Examiner is invited to contact the undersigned at the number listed below.

Respectfully submitted,



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